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**UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office**

August 02, 2004

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THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.**

APPLICATION NUMBER: 60/458,227

FILING DATE: March 27, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/09358

**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**



M. Tarver

**M. TARVER
Certifying Officer**

**PRIORITY
DOCUMENT**

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

03/27/03

3-28-3

60458227 1A/PROV

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

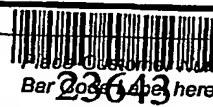
PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV036313487US

PTO
30996 U.S. PTO
60/458227

03/27/03

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname		Residence (City and either State or Foreign Country)	
Thomas J. Jeremiah U.		Webster Ejlofor		West Lafayette, IN West Lafayette, IN	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max) TITANIUM AND TITANIUM ALLOY NANOPARTICLES AS ORTHOPEDIC BIOMATERIAL					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		23643		 Please Customer Number Bar 23643 here PATENT TRADEMARK OFFICE	
OR Type Customer Number here					
<input type="checkbox"/> Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country		Telephone (317) 231-7253		Fax	(317) 231-7433
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		5		<input type="checkbox"/> CD(s), Number	
<input type="checkbox"/> Drawing(s) Number of Sheets				<input checked="" type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76				Postcard	
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number		10-0435		\$80.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input type="checkbox"/> No.					
<input checked="" type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: National Science Foundation, Grant/Contract Title:					

Respectfully submitted,

SIGNATURE

Date 3/27/03

TYPED or PRINTED NAME Bradford G. Addison

REGISTRATION NO. 41,486

TELEPHONE (317) 231-7253

(if appropriate)

Docket Number:

3220-72619

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

BARNES & THORNBURG

11 South Meridian Street
Indianapolis, IN 46204
(317) 236-1313
(317) 231-7433 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: Unknown
Confirmation No.: Unknown
Application No.: Unknown
Invention: TITANIUM AND TITANIUM ALLOY
NANOPARTICLES AS ORTHOPEDIC
BIOMATERIAL
Applicant: Thomas J. Webster et al.
Filed: Herewith (March 27, 2003)
Attorney
Docket: 3220-72619
Examiner: Unknown

CERTIFICATE UNDER 37 C.F.R. § 1.10

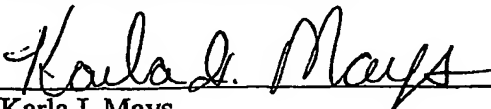
BOX Provisional Patent Application
Commissioner for Patents
Washington, D.C. 20231

Sir:

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231, on March 27, 2003. The Express Mail mailing label number is EV036313487US.

Respectfully submitted,

BARNES & THORNBURG


Karla I. Mays

BGA/kim
Indianapolis, IN
(317) 231-7253

<h1 style="margin: 0;">FEE TRANSMITTAL</h1> <h2 style="margin: 0;">for FY 2003</h2> <p style="font-size: small; margin: 0;">Effective 01/01/2003. Patent fees are subject to annual revision.</p>		Complete if Known	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Application Number	Unknown
		Filing Date	Herewith (March 27, 2003)
		First Named Inventor	Thomas J. Webster et al.
		Examiner Name	Unknown
		Group Art Unit	Unknown
TOTAL AMOUNT OF PAYMENT (\$) \$80.00		Attorney Docket No.	3220-72619

<p>METHOD OF PAYMENT (check all that apply)</p> <p> <input checked="" type="checkbox"/> Check <input type="checkbox"/> Credit card <input type="checkbox"/> Money Order <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p> <input type="checkbox"/> Deposit Account: Deposit Account Number: 10-0435 Deposit Account Name: BARNES & THORNBURG </p> <p>The Commissioner is authorized to: (check all that apply)</p> <p> <input type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) <i>due to dependency of this application</i> <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account. </p> <p style="text-align: center;">FEE CALCULATION</p> <p>1. BASIC FILING FEE</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1001</td> <td>750</td> <td>2001</td> <td>375</td> <td>Utility filing fee</td> <td></td> </tr> <tr> <td>1002</td> <td>330</td> <td>2002</td> <td>165</td> <td>Design filing</td> <td></td> </tr> <tr> <td>1003</td> <td>520</td> <td>2003</td> <td>260</td> <td>Plant filing fee</td> <td></td> </tr> <tr> <td>1004</td> <td>750</td> <td>2004</td> <td>375</td> <td>Reissue filing</td> <td></td> </tr> <tr> <td>1005</td> <td>180</td> <td>2005</td> <td>80</td> <td>Provisional filing fee</td> <td style="text-align: right;">\$0.00</td> </tr> <tr> <td colspan="5" style="text-align: right;">SUBTOTAL (1)</td> <td style="text-align: right;">(\$) \$80.00</td> </tr> </tbody> </table> <p>2. EXTRA CLAIM FEES FOR UTILITY AND</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th colspan="2">Total Claims</th> <th colspan="2">Extra Claims</th> <th colspan="2">Fee from below</th> <th colspan="2">Fee Paid</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td>-20** =</td> <td>0</td> <td>X</td> <td></td> <td>=</td> <td>0.00</td> </tr> <tr> <td></td> <td></td> <td>-3** =</td> <td>0</td> <td>X</td> <td></td> <td>=</td> <td>0.00</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1202</td> <td>18</td> <td>2202</td> <td>9</td> <td>Claims in excess of 20</td> <td></td> </tr> <tr> <td>1201</td> <td>84</td> <td>2201</td> <td>42</td> <td>Independent claims in excess of 3</td> <td></td> </tr> <tr> <td>1203</td> <td>280</td> <td>2203</td> <td>140</td> <td>Multiple dependent claim, if not paid</td> <td></td> </tr> <tr> <td>1204</td> <td>84</td> <td>2204</td> <td>42</td> <td>** Reissue independent claims over original patent</td> <td></td> </tr> <tr> <td>1205</td> <td>18</td> <td>2205</td> <td>9</td> <td>** Reissue claims in excess of 20 and over original patent</td> <td></td> </tr> <tr> <td colspan="5" style="text-align: right;">SUBTOTAL (2)</td> <td style="text-align: right;">(\$) \$0.00</td> </tr> </tbody> </table> <p><small>**or number previously paid, if greater; For Reissues, see above</small></p>	Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1001	750	2001	375	Utility filing fee		1002	330	2002	165	Design filing		1003	520	2003	260	Plant filing fee		1004	750	2004	375	Reissue filing		1005	180	2005	80	Provisional filing fee	\$0.00	SUBTOTAL (1)					(\$) \$80.00	Total Claims		Extra Claims		Fee from below		Fee Paid				-20** =	0	X		=	0.00			-3** =	0	X		=	0.00	Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1202	18	2202	9	Claims in excess of 20		1201	84	2201	42	Independent claims in excess of 3		1203	280	2203	140	Multiple dependent claim, if not paid		1204	84	2204	42	** Reissue independent claims over original patent		1205	18	2205	9	** Reissue claims in excess of 20 and over original patent		SUBTOTAL (2)					(\$) \$0.00	<p>3. ADDITIONAL FEES</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th colspan="2">Large Entity</th> <th colspan="2">Small Entity</th> <th rowspan="2">Fee Description</th> <th rowspan="2">Fee Paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1051</td> <td>130</td> <td>2051</td> <td>65</td> <td>Surcharge - late filing fee or oath</td> <td></td> </tr> <tr> <td>1052</td> <td>50</td> <td>2052</td> <td>25</td> <td>Surcharge - late provisional filing fee or cover sheet</td> <td></td> </tr> <tr> <td>1053</td> <td>130</td> <td>1053</td> <td>130</td> <td>Non - English specification</td> <td></td> </tr> <tr> <td>1812</td> <td>2,520</td> <td>1812</td> <td>2,520</td> <td>For filing a request for <i>ex parte</i> reexamination</td> <td></td> </tr> <tr> <td>1804</td> <td>920*</td> <td>1804</td> <td>920*</td> <td>Requesting publication of SIR prior to Examiner action</td> <td></td> </tr> <tr> <td>1805</td> <td>1,840*</td> <td>1805</td> <td>1,840*</td> <td>Requesting publication of SIR after Examiner action</td> <td></td> </tr> <tr> <td>1251</td> <td>110</td> <td>2251</td> <td>55</td> <td>Extension for reply within first month</td> <td></td> </tr> <tr> <td>1252</td> <td>410</td> <td>2252</td> <td>205</td> <td>Extension for reply within second month</td> <td></td> </tr> <tr> <td>1253</td> <td>930</td> <td>2253</td> <td>465</td> <td>Extension for reply within third month</td> <td></td> </tr> <tr> <td>1254</td> <td>1,450</td> <td>2254</td> <td>725</td> <td>Extension for reply within fourth month</td> <td></td> </tr> <tr> <td>1255</td> <td>1,970</td> <td>2255</td> <td>985</td> <td>Extension for reply within fifth month</td> <td></td> </tr> <tr> <td>1401</td> <td>320</td> <td>2401</td> <td>160</td> <td>Notice of Appeal</td> <td></td> </tr> <tr> <td>1402</td> <td>320</td> <td>2402</td> <td>160</td> <td>Filing a brief in support of an appeal</td> <td></td> </tr> <tr> <td>1403</td> <td>280</td> <td>2403</td> <td>140</td> <td>Request for oral hearing</td> <td></td> </tr> <tr> <td>1451</td> <td>1,510</td> <td>1451</td> <td>1,510</td> <td>Petition to institute a public use proceeding</td> <td></td> </tr> <tr> <td>1452</td> <td>110</td> <td>2452</td> <td>55</td> <td>Petition to revive - unavoidable</td> <td></td> </tr> <tr> <td>1453</td> <td>1,300</td> <td>2453</td> <td>650</td> <td>Petition to revive - unintentional</td> <td></td> </tr> <tr> <td>1501</td> <td>1,300</td> <td>2501</td> <td>650</td> <td>Utility issue fee (or reissue)</td> <td></td> </tr> <tr> <td>1502</td> <td>470</td> <td>2502</td> <td>235</td> <td>Design issue fee</td> <td></td> </tr> <tr> <td>1503</td> <td>630</td> <td>2503</td> <td>315</td> <td>Plant issue fee</td> <td></td> </tr> <tr> <td>1460</td> <td>130</td> <td>1460</td> <td>130</td> <td>Petitions to the Commissioner</td> <td></td> </tr> <tr> <td>1807</td> <td>50</td> <td>1807</td> <td>50</td> <td>Processing fee under 37 CFR § 1.17(q)</td> <td></td> </tr> <tr> <td>1808</td> <td>180</td> <td>1808</td> <td>180</td> <td>Submission of Information Disclosure Statement</td> <td></td> </tr> <tr> <td>8021</td> <td>40</td> <td>8021</td> <td>40</td> <td>Recording each patent assignment per property (times number of properties)</td> <td></td> </tr> <tr> <td>1809</td> <td>750</td> <td>2809</td> <td>375</td> <td>Filing a submission after final rejection (37 CFR § 1.129(a))</td> <td></td> </tr> <tr> <td>1810</td> <td>750</td> <td>2810</td> <td>375</td> <td>For each additional invention to be examined (37 CFR § 1.129(b))</td> <td></td> </tr> <tr> <td>1801</td> <td>750</td> <td>2801</td> <td>375</td> <td>Request for Continued Examination (RCE)</td> <td></td> </tr> <tr> <td>1802</td> <td>900</td> <td>1802</td> <td>900</td> <td>Request for expedited examination of a design application</td> <td></td> </tr> </tbody> </table> <p>Other fee (specify) _____</p> <p style="text-align: right;">SUBTOTAL (3) (\$) _____</p> <p><small>*Reduced by Basic Filing Fee Paid</small></p>	Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1051	130	2051	65	Surcharge - late filing fee or oath		1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet		1053	130	1053	130	Non - English specification		1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination		1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action		1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action		1251	110	2251	55	Extension for reply within first month		1252	410	2252	205	Extension for reply within second month		1253	930	2253	465	Extension for reply within third month		1254	1,450	2254	725	Extension for reply within fourth month		1255	1,970	2255	985	Extension for reply within fifth month		1401	320	2401	160	Notice of Appeal		1402	320	2402	160	Filing a brief in support of an appeal		1403	280	2403	140	Request for oral hearing		1451	1,510	1451	1,510	Petition to institute a public use proceeding		1452	110	2452	55	Petition to revive - unavoidable		1453	1,300	2453	650	Petition to revive - unintentional		1501	1,300	2501	650	Utility issue fee (or reissue)		1502	470	2502	235	Design issue fee		1503	630	2503	315	Plant issue fee		1460	130	1460	130	Petitions to the Commissioner		1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)		1808	180	1808	180	Submission of Information Disclosure Statement		8021	40	8021	40	Recording each patent assignment per property (times number of properties)		1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))		1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))		1801	750	2801	375	Request for Continued Examination (RCE)		1802	900	1802	900	Request for expedited examination of a design application	
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1451	1,510	1451	1,510	Petition to institute a public use proceeding																																																																																																																																																																																																																																																																																																			
1452	110	2452	55	Petition to revive - unavoidable																																																																																																																																																																																																																																																																																																			
1453	1,300	2453	650	Petition to revive - unintentional																																																																																																																																																																																																																																																																																																			
1501	1,300	2501	650	Utility issue fee (or reissue)																																																																																																																																																																																																																																																																																																			
1502	470	2502	235	Design issue fee																																																																																																																																																																																																																																																																																																			
1503	630	2503	315	Plant issue fee																																																																																																																																																																																																																																																																																																			
1460	130	1460	130	Petitions to the Commissioner																																																																																																																																																																																																																																																																																																			
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)																																																																																																																																																																																																																																																																																																			
1808	180	1808	180	Submission of Information Disclosure Statement																																																																																																																																																																																																																																																																																																			
8021	40	8021	40	Recording each patent assignment per property (times number of properties)																																																																																																																																																																																																																																																																																																			
1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))																																																																																																																																																																																																																																																																																																			
1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))																																																																																																																																																																																																																																																																																																			
1801	750	2801	375	Request for Continued Examination (RCE)																																																																																																																																																																																																																																																																																																			
1802	900	1802	900	Request for expedited examination of a design application																																																																																																																																																																																																																																																																																																			

SUBMITTED BY		Complete (if applicable)	
Name (Print/Type)	Bradford G. Addison	Registration No. (Attorney/Agent)	41,486
Signature		Telephone	(317) 231-7253
		Date	3/27/03

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PROVISIONAL PATENT APPLICATION

of

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and

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for

TITANIUM AND TITANIUM ALLOY NANOPARTICLES
AS ORTHOPEDIC BIOMATERIAL

PRF Docket No. P-03032.P1

Attorney Docket 3220-72619

TITANIUM AND TITANIUM ALLOY NANOPARTICLES AS ORTHOPEDIC BIOMATERIAL

FIELD OF THE DISCLOSURE

The present disclosure generally relates to a composition for use as a prosthetic biomaterial and an associated method. The present disclosure particularly relates to a prosthetic biomaterial that includes titanium and titanium alloy nanoparticles and an associated method.

BACKGROUND OF THE DISCLOSURE

Biomaterials commonly used in orthopedic prosthetic applications are not designed to retain functionality while maintaining compatibility with respect to biological factors at the implant/tissue interface. In order to achieve proper cytocompatibility, it is desirable to determine the biomaterial surface characteristics that interface optimally with the pertinent bone cell types. Achieving similar mechanical properties to native tissue ensures limited destruction of local cells. Surface texture is also important to control for orthopedic implant efficacy to closely harmonize with the mass and kinetics of osseous biomolecular events.

DETAILED DESCRIPTION OF THE DISCLOSURE

While the disclosure is susceptible to various modifications and alternative forms, specific embodiments will herein be described in detail. It should be understood, however, that there is no intent to limit the disclosure to the particular forms described, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

The current disclosure involves the use of nanoparticles of Ti and Ti alloy (specifically, Ti6Al4V) as more effective bone tissue biomaterials. Nanoparticulates (size range: less than 200 nm) have high surface reactivity. In their properly consolidated conditions, nanoparticles result in increased elastic modulus and strength as well as in nanostructured grains. Material formulations developed in our laboratory contain highly nanostructured crystal grains

fabricated out of their corresponding nanoparticles, and possess properties (cytocompatibility and mechanical) that are appropriate for different orthopedic applications in the skeletal system. Most importantly, the designed nanophase titanium and its alloy significantly increase functions of cells that are responsible for bone cell adhesion and bone tissue regeneration. Significantly increased adhesion and differentiation of bone cells as well as mineralization of the tissue are desirable to result in efficient and effective implant function. For these reasons, nanoparticles of Ti and Ti6Al4V are desirable (as they very closely match the mass and kinetics of bone/bodily fluid biomolecular reactions and enhance osseous functions) for the next generation of orthopedic prosthetic implants.

In particular, constructs of Ti and Ti6Al4V nanoparticles in their green or consolidated conditions and possessing nano grain size and/or nano porosity simulate the nanometer dimensions of components of the bone tissue and body molecules. Formulations of Powder Metallurgy Titanium and Titanium Alloy from their nanoparticles possess enhanced surface and mechanical properties to increase performance of bone fixation and total bone replacements. Nanometer dimensions of the Ti and Ti6Al4V grains and the nanoscale, equidispersed morphology of their surfaces, optimize both surface and mechanical requirements. These nanophase formulations significantly promote sustained bone cell adhesion and differentiation, a major requirement to efficient integration of implant with juxtaposed tissues. Current Ti and Ti6Al4V implants materials frequently fail to maintain long-term biointegration with the body tissue, quickly leading to failures at the interface. In contrast, nanoparticles of these metals simulate the nano dimensions of cellular molecules, promoting bone cell adhesion, proliferation and long term functions that sustain implant-bone interface integrity. Accordingly, an orthopedic prosthetic device which includes nanoparticles of these metals can be utilized in a method for implanting such a device in the body of an animal.

While the disclosure has been illustrated and described in detail in the foregoing description, such an illustration and description is to be considered as exemplary and not restrictive in character, it being understood that only the illustrative embodiments have been

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described and that all changes and modifications that come within the spirit of the disclosure are desired to be protected.

ABSTRACT OF THE DISCLOSURE

A composition for use as a prosthetic biomaterial and an associated method is described.